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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,745	07/12/2000	SUZANNE CORY	13464	7536

7590 09/25/2003

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EXAMINER	
BERTOGLIO, VALARIE E	

ART UNIT	PAPER NUMBER
1632	14

DATE MAILED: 09/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/508,745	CORY ET AL.	
	Examiner	Art Unit	
	Valarie Bertoglio	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

After further consideration, the previous office action mailed 01/29/2003, paper # 11, has been vacated and replaced with the instant office action.

Response to Amendment

Applicant's amendment filed on 07/03/2003 has been entered. Claim 10 has been amended and is considered in the restriction as set forth below.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

It is noted that claims 3 and 4 are drawn to modification of Bcl-2 protein whereas other claims are drawn to Bcl-w protein. It appears that recitation of Bcl-2 is an inadvertent typographical error. For the purposes of this restriction, Bcl-2 is being interpreted as Bcl-w.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s), 1-3, 6-8 and 20, drawn to an animal or avian species modified through non-transgenic mechanisms to have reduced levels of Bcl-w protein.

Group II, claim(s), 1-3 and 6-8 10,11,14-16 and 20, drawn to a genetically modified animal or avian species having reduced levels of Bcl-w protein as an effect of a non-bcl-w transgene or transgene encoding a bcl-w antisense molecule.

Group III, claim(s), 1-3, 9, and 12-20, drawn to a genetically modified animal or avian species having reduced levels of Bcl-w protein as an effect of a genetically modified, endogenous bcl-w gene.

Group IV, claim(s), 1,4,5 and 20, drawn to an animal or avian species modified through non-transgenic mechanisms to have reduced levels of a Bcl-w associated protein.

Group V, claim(s), 1,4,5 14, 15 and 18, drawn to a genetically modified animal or avian species having reduced levels of a Bcl-w-associated protein as an effect of a non-bcl-w transgene.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Unity of invention between different categories of inventions will only be found to exist if the specific combinations of inventions are present. Those combinations include:

1) A product and a special process of manufacture of said product.

2) A product and a process of use of said product.

3) A product, a special process of manufacture of said product, and a process of use of said product.

4) A process and an apparatus specially designed to carry out said process.

5) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said products, and methods of making multiple products as claimed in the instant application, see MPEP § 1850. Groups I-V represent different products with distinct material compositions and uses. Groups I and II encompass an animal modified through non-transgenic mechanisms to alter Bcl-w protein levels(Group I) or Bcl-w associated protein levels (Group II). Animals

encompassed by these groups can include those administered drugs or those altered by some other means that does not alter the genetic make-up of the animal such as gene therapy. Groups III-V encompass transgenic animals with an altered genome. Group III includes animals with an altered endogenous Bcl-w gene. Group IV encompasses animals with alteration in a gene other than Bcl-w or with a transgene encoding a bcl-w antisense molecule. Group V encompasses transgenic animals having reduced levels of a bcl-w associated protein.

Furthermore, PCT Rule 13.2 requires that unity of invention exists only when there is a shared or corresponding technical feature among the claimed inventions. Groups I and IV is directed to methods of affecting a bcl-w related protein, which has the special technical feature of a bcl-w associated protein. Groups II-V are directed to methods of affecting Bcl-w which has a special technical feature of Bcl-w.

Sequence Election Requirement

Claims 2,3,12,20 read on patentably distinct Groups drawn to multiple SEQ ID Numbers. Each of the SEQ ID Nos 1-5 and 7, constitutes independent inventions, which are patentably distinct because each of the sequences are unrelated, as such a further restriction is applied to the sequences. For an elected Group drawn to a SEQ ID NO, the Applicants must further elect a single nucleotide and the corresponding polypeptide sequence.

MPEP 803.04 states:

> Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the

> requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996).

Although the MPEP deems that up to ten nucleotide sequences may be searched without restriction, it has recently been decided by the Director of Biotechnology at the USPTO that searching more than one sequence per application will place an undue burden upon the Examiner and the Office. For this reason, restriction to ONE SEQUENCE is being applied to all applications at this time.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

PETER PARAS
PATENT EXAMINER

Valarie Bertoglio
Patent Examiner